

5/5/99

K991194

## Appendix D

### Special 510(k) Summary HyTek™ Guidewire (Prepared in accordance with 21 CFR part 807.92)

510(k) Number: K991194

1. Submitter: Prepared and Submitted by:  
MICROVENA Corporation  
Angela Mallery  
Sr. Regulatory Affairs Associate  
651-777-6700  
1861 Buerkle Road  
White Bear Lake, MN 55110
2. Device Name: Guidewire  
Trade Name: HyTek™ Guidewire  
Classification Name: Wire, Guide, Catheter  
Classification Code: 74 DQX
3. Substantial Equivalency: The HyTek guidewire is substantially equivalent to K922060.
4. Device Description and Intended Use:  
The MICROVENA HyTek Guidewire is designed to fit inside a catheter, for directing the catheter through a blood vessel.  
  
The main body of the guidewire is constructed of Nitinol. The distal tip is a helical coiled wire wound around the inner core. The guidewire is coated with a hydrophilic coating to facilitate smoother passage.  
  
The HyTek Guidewire is available in diameters of .014" to .025, and in lengths from 80 cm to 300 cm.
5. Technological Characteristics  
MICROVENA's HyTek guidewire has the same indications for use and is technically the same as the predicate device.
6. Non-Clinical Tests  
The results of these tests demonstrate the functionality and performance characteristics of the guidewire are comparable to the currently marketed device. These tests included: torque, flexibility, and coating adherence.
7. Conclusions  
Based on information presented in this 510(k) premarket notification, MICROVENA guidewires are considered substantially equivalent to the currently marketed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 5 1999

Ms. Angela Mallery  
Sr. Regulatory Affairs Associate  
MICROVENA Corporation  
1861 Buerkle Road  
White Bear Lake, MN 55110

Re: K991194  
Trade Name: HyTek™ Guidewire  
Regulatory Class: II  
Product Code: DQX  
Dated: April 7, 1999  
Received: April 8, 1999

Dear Ms. Mallery:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices

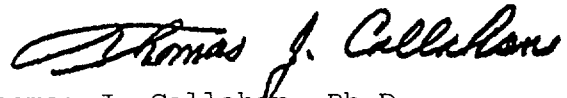
Page 2 - Ms. Angela Mallery

under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Appendix B

### *Indications for Use*

510(k) Number (if known):

K991194

Device Name:

HyTek Guidewire

Indications for Use:

The 0.025" HyTek guidewire is indicated for use in the peripheral vasculature. The 0.014", 0.016", and 0.018" HyTek Guidewires are indicated for use in the peripheral and coronary vasculature.

Please do NOT write below this line - CONTINUE on ANOTHER page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  
(Optional Format 1-2-96)

L. G. Smith for Sloan 5/4/99  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

HyTek Guidewire Supplementary Information  
April 30, 1999  
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